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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,762	12/11/2003	John B. Enns	VTN 568 CIP3	1967
27777	7590	01/23/2008	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HUYNH, CARLIC K	
			ART UNIT	PAPER NUMBER
			1612	
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			01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,762

Applicant(s)

ENNS ET AL.

Examiner

Carlic K. Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

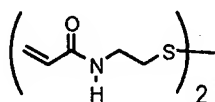
Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :27 August 2004, 16 September 2005, 11 October 2005, and 24 July 2007.

DETAILED ACTION*Status of the Claims*

1. Claims 1-44 are pending in the application in response to the restriction requirement submitted on October 9, 2007. Accordingly, claims 1-44 are being examined on the merits herein.

Election/Restrictions

2. Applicants' election of: (1) a ligand monomer of formula (I),



as the species of a ligand monomer; and (2) senofilcon A as the species of a lens, in the reply filed on November 9, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 23 and 36-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on November 9, 2007.

Accordingly, claims 1-22 and 24-35 are examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statements submitted on August 27, 2004, September 16, 2005, October 11, 2005, and July 24, 2007, are acknowledged.

Drawings

3. The drawings are objected to because of typographical errors. In the instant case, figures 1-4 contain "Figur" in the figure headings. "Figur" is spelled incorrectly and should be "Figure". Moreover, in figures 1-3, "HEMA" and "CYST" are not clear as to what chemicals they represent. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract contains legal phraseology, namely "said".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

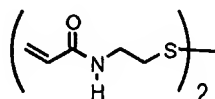
5. Claims 1-22 and 24-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (US 5,451,651) in view of Nochumson (US 4,542,200), Monestere (US 4,923,480), and Rudnick (US 2,321,046).

Lai teaches contact lens materials (abstract). The contact lens comprises a monomeric mixtures of divinyl monomers such as divinylbenzene and allyl methacrylate, etc. (column 5, lines 4-10).

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Lai does not explicitly teach N,N'-(bisacylyl)cystamine. Lai also does not teach a silver solution and senofilcon A.

Nochumson is solely used to teach that N,N'-bisacylylcystamine is a divinyl monomer (column 1, lines 57-61). Thus it would be obvious that N,N'-bisacylylcystamine can be the divinyl monomer in the contact lens of Lai. It is noted that the structure of N,N'-bisacylylcystamine is known in the art as,



Monestere teaches opaquing and tinting a contact lens using a sprayer to coat the contact lens with an opaquing metal salt in liquid form such as silver nitrate (abstract; and column 2, lines 35-38). The contact lens is soaked in a solution of silver nitrate for 5 seconds or more (column 2, lines 44-45). Monestere further teaches soft contact lenses are formed from hydrogels.

It is noted that applicants have disclosed in the instant specification that it is well known in the prior art that soft contact lenses are commercially available as etafilcon A, genfilcon A, lenefilcon A, polymacon, aquafilcon A, balafilcon A, galyfilcon A, senofilcon A and Iotrafilcon A, silicone hydrogels, etc. (page 21 lines 3-14). Thus it would obvious that the soft contact lenses taught by Monestere can be senofilcon A and silicone hydrogels.

Rudnick is solely used to teach that silver nitrate is well known in the photographic and film development arts to be a light-sensitive material (page 2, left column, lines 61-62). Thus it would be obvious that the silver nitrate used in Monestere is light-sensitive.

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Accordingly, absent the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Lai to contain silver nitrate solution and senofilcon A because the compounds of Monestere are silver nitrate and senofilcon A and according to Monestere, a silver nitrate and senofilcon A can be used to make a contact lens.

The motivation to combine the compounds of Lai to the compounds of Monestere is that the compounds of Monestere are compositions comprising silver nitrate and senofilcon A and that such compositions can be used to make a contact lens.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding the photoinitiator concentration and light intensity sufficient to provide the reactivity ratio of at least 0.45 as recited in instant claims 1 and 30-35, Monestere teaches silver nitrate, which is well known to be light-sensitive (column 2, lines 35-38), which closely meets the photoinitiator concentration and light intensity sufficient to provide the reactivity ratio of at least 0.45 in the composition set forth in instant claims 1 and 30-35. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of silver nitrate and light provided in a composition, according to the guidance set forth in Monestere, to provide a composition having the desired silver nitrate content and light intensity. It is noted that "[W]here the general conditions of a claim are

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disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the concentration of the silver solution and the time of exposure to the silver solution as recited in instant claims 1, 3, 16-18, 20, 24, and 26-27, Monestere teaches silver nitrate contact lens is soaked in a solution of silver nitrate for 5 seconds or more (column 2, lines 35-38 and 44-45), which closely meets the concentration of the silver solution and the time of exposure to the silver solution in the composition set forth in instant claims 1, 3, 16-18, 20, 24, and 26-27. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the concentration of the silver solution and the time of exposure to the silver solution provided in a composition, according to the guidance set forth in Monestere, to provide a composition having the desired concentration of the silver solution and the time of exposure to the silver solution. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the concentration of the compound of formula (I) as recited in instant claims 1, 4-5, 9-11, and 20, Lai teaches the contact lens comprises a monomeric mixtures of divinyl monomers (column 5, lines 4-10) and Nochumson teaches N,N'-bisacylylcystamine is a divinyl monomer (column 1, lines 57-61), which closely meets the concentration of the compound of formula (I) in the composition set forth in instant claims 1, 4-5, 9-11, and 20. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the compound of formula (I) provided in a

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composition, according to the guidance set forth in *Lai* and *Nochumson*, to provide a composition having desired compound of formula (I) content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Double Patenting

Statutory-Type

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-44 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-44 of copending Application Meyers et al. (10/703,770). This is a provisional double patenting rejection since the conflicting claims have not been patented.

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 7-8, 13, 15, 19, and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of copending Application Neely et al. (10/183,883).

The instant claims are directed at method steps comprising curing a contact lens with a monomer mix comprising senofilcon A and treating the contact lens with a silver solution comprising silver nitrate

Claims 1 and 9 of Neely et al. are directed to a method of producing an antimicrobial lens comprising silver nitrate.

The instant claims and the claims of Neely et al. are obvious because the instant claims disclose silver nitrate. Moreover, it would be obvious that the lens of Neely et al. can be a contact lens comprising of senofilcon A.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

8. Claims 1, 7-8, 13, 15, 19, and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, and 23-24 of copending Application Rathore et al. (10/715,745), claims 1, 10-11, and 17 of copending

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Application Andersson et al. (10/715,903), claims 1-3, 9-12, and 18 of copending Application Neely et al. (10/748,621), and claims 1 and 7-10 of copending Application Nayiby et al. (10/882,072). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 9, and 23-24 of Rathore et al., claims 1, 10-11, and 17 of Andersson et al., claims 1-3, 9-12, and 18 of Neely et al., and claims 1 and 7-10 of Nayiby et al. are directed at a contact lens comprising of senofilcon A and a silver compound, which is the same contact lens comprising of senofilcon A and a silver compound used in the method steps of instant claims 1, 7-8, 13, 15, 19, and 21.

In further regards to the copending Application Nayiby et al., claims 1 and 7-10 are directed at a packaging solution comprising a contact lens comprising an antimicrobial metal salt. It would be obvious the contact lens may be a soft contact lens comprising senofilcon A and the antimicrobial metal salt may be silver nitrate.

Thus the contact lens comprising of senofilcon A and a silver compound is not patentably distinct between Rathore et al., Andersson et al., Neely et al., Nayiby et al. and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

9. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh



SHENGJUN WANG
PRIMARY EXAMINER